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# A BILL FOR AN ACT

RELATING TO THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTH CARE.

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:**

1           SECTION 1. Chapter 321, Hawaii Revised Statutes, is  
2 amended by adding a new part to be appropriately designated and  
3 to read as follows:

4           **"PART           .   ARTIFICIAL INTELLIGENCE IN HEALTH CARE**

5           **§321-       Definitions.** As used in this part:

6           "Artificial intelligence" or "artificial intelligence  
7 system" means any engineered or machine-based system that varies  
8 in its level of autonomy and that can, for explicit or implicit  
9 objectives, infer from the input it receives how to generate  
10 outputs that can influence physical or virtual environments.

11          "Authorized representative" means:

12          (1) An agent, a guardian, or a surrogate of the patient;

13                 or

14          (2) A person who is given a written individual instruction

15                 or power of attorney for health care in the patient's

16                 advance health-care directive pursuant to chapter

17                 327E.



1 For the purposes of this definition, "advance health-care  
2 directive", "agent", "guardian", "power of attorney for health  
3 care", and "surrogate" have the same meanings as defined in  
4 section 327E-2.

5 "Consequential decision" means a decision that has a  
6 significant effect on the physical or mental health of a  
7 patient.

8 "Department" means the department of health.

9 "Health care provider" and "health care service" have the  
10 same meanings as those terms are defined in section 323D-2.

11 "Health information" and "individually identifiable health  
12 information" have the same meanings as those terms are defined  
13 in section 323B-2.

14 "Patient" means a person who is under the observation and  
15 care of or otherwise receiving health care services from a  
16 health care provider.

17 "Personal data" means any information that is linked or  
18 could be reasonably linkable to an identified or identifiable  
19 natural person. "Personal data" does not include de-identified  
20 data or publicly available information.



1 "Profiling" means any form of automated processing  
2 performed on personal data to evaluate, analyze, or predict  
3 personal aspects related to an identified or identifiable  
4 individual's economic situation, health, personal preferences,  
5 interests, reliability, behavior, location, or movements.

6 "Remote communication" means communication through means by  
7 which a person who is not physically present in the same  
8 location as a health care provider may communicate with the  
9 health care provider on a substantially simultaneous basis.

10 "Remote communication" includes telecommunication,  
11 videoconference, and electronic communication, including  
12 internet-based communication and electronic transmission.

13 "Substantial factor" means a factor that:

- 14 (1) Assists in making a consequential decision;
- 15 (2) Is capable of altering the outcome of a consequential  
16 decision; and
- 17 (3) Is generated by an artificial intelligence system.

18 "Substantial factor" includes any use of an artificial  
19 intelligence system to generate any content, decision,  
20 prediction, or recommendation concerning a patient that is used



1 as a basis to make a consequential decision concerning the  
2 patient.

3       **§321- Patient interaction; disclosure.** (a) Any health  
4 care provider that uses or makes available for use an artificial  
5 intelligence system intended to interact with patients by means  
6 of remote communication shall disclose to the patient or the  
7 patient's authorized representative, as applicable, that the  
8 person is interacting with artificial intelligence.

9       (b) The disclosure shall be made before or at the time of  
10 the interaction; provided that in the case of an emergency, the  
11 disclosure shall be made as soon as reasonably possible.

12       (c) The disclosure shall be clear and conspicuous, and  
13 include:

14       (1) A disclaimer that:

15               (A) The communication was generated by artificial  
16 intelligence; or

17               (B) The communication was generated by artificial  
18 intelligence and reviewed by a health care  
19 provider who is a natural person or a natural  
20 person retained by the health care provider; and



1 (2) Clear instructions on how the patient can directly  
2 contact a health care provider who is a natural  
3 person, an employee of the health care provider, or  
4 other appropriate natural person.

5 **§321- Consequential decisions; notice; statement; opt-**  
6 **out; corrections; appeal.** (a) Before using an artificial  
7 intelligence system to make, or be a substantial factor in  
8 making, a consequential decision, a health care provider shall  
9 provide the patient or the patient's authorized representative,  
10 as applicable, with a written notice that:

11 (1) Informs the recipient that the health care provider  
12 will be using an artificial intelligence system to  
13 make, or be a substantial factor in making, the  
14 consequential decision;

15 (2) Discloses the purpose of the artificial intelligence  
16 system and the nature of the consequential decision;

17 (3) Describes the artificial intelligence system in plain  
18 language; and

19 (4) Allows the patient to opt out of the processing of the  
20 patient's individually identifiable health information  
21 or other personal data for purposes of profiling in



1 furtherance of decisions that have legal or similarly  
2 significant effects concerning the patient.

3 (b) Any health care provider that used an artificial  
4 intelligence system to make, or be a substantial factor in  
5 making, a consequential decision shall provide the patient or  
6 the patient's authorized representative, as applicable, with:

7 (1) A written statement that describes the consequential  
8 decision and the principal reasons for the  
9 consequential decision, including:

10 (A) The degree to which, and manner in which, the  
11 artificial intelligence system contributed to the  
12 consequential decision;

13 (B) The type of data that was processed by the  
14 artificial intelligence system in making the  
15 consequential decision; and

16 (C) The sources of the data described in  
17 paragraph (B);

18 (2) An opportunity to correct any incorrect health  
19 information or personal data that the artificial  
20 intelligence system processed in making, or as a



1           substantial factor in making, the consequential  
2           decision; and  
3           (3) An opportunity to appeal the consequential decision,  
4           including allowing, to the extent technically  
5           feasible, human review of all information relating to  
6           the consequential decision; provided that this  
7           paragraph shall not apply if providing the opportunity  
8           for appeal is not in the best interest of the patient,  
9           including in instances in which any delay might pose a  
10          risk to the life or safety of the patient.

11          (c) The notice and statement required pursuant to  
12          subsections (a) and (b), respectively, shall be provided  
13          directly to the patient or the patient's authorized  
14          representative, as applicable; provided that if the health care  
15          provider is unable to comply with this requirement, the health  
16          care provider shall provide the notice or statement in a manner  
17          that is reasonably calculated to ensure that the patient or the  
18          patient's authorized representative, as applicable, receives the  
19          notice or statement.

20          **§321- Consequential decisions; review and validation by**  
21          **qualified oversight personnel.** (a) Any health care provider



1 that uses an artificial intelligence system to make, or be a  
2 substantial factor in making, a consequential decision shall  
3 maintain an artificial intelligence oversight personnel.

4 (b) The artificial intelligence oversight personnel:

5 (1) Shall be a natural person;

6 (2) Shall have the qualifications, experience, and  
7 expertise necessary to effectively evaluate outputs,  
8 including but not limited to any information, data,  
9 assumptions, predictions, scoring, recommendations,  
10 decisions, or conclusions generated by artificial  
11 intelligence systems in the field of health care; and

12 (3) May be retained by contracting with a third-party.

13 (c) The artificial intelligence oversight personnel shall:

14 (1) Monitor the artificial intelligence systems used by  
15 the health care provider; and

16 (2) Before the health care provider uses an output  
17 generated by an artificial intelligence system to  
18 make, or be a substantial factor in making, a  
19 consequential decision:

20 (A) Review and evaluate the output; and

21 (B) Validate or override the output.



1           §321-     **Monitoring; performance evaluation; record**  
2 **keeping.** Any health care provider that uses an artificial  
3 intelligence system to make, or be a substantial factor in  
4 making, a consequential decision shall:

5           (1) Monitor the usage of artificial intelligence systems  
6                 to make, or be a substantial factor in making,  
7                 consequential decisions;

8           (2) Conduct regular performance evaluations of the  
9                 artificial intelligence systems, including the  
10                assessment of:

11                (A) Potential biases;

12                (B) Risks to the safety and rights of patients,  
13                         including the confidentiality of personal data;  
14                         and

15                (C) Mitigation strategies for any identified risks;

16           (3) Implement procedures to address any deficiencies  
17                 identified through the monitoring or performance  
18                 evaluations, including the suspension or recalibration  
19                 of any artificial intelligence system; and

20           (4) Maintain:



- 1 (A) An updated inventory of the artificial  
2 intelligence systems;
- 3 (B) Documentation on the system design, intended use,  
4 and training data of the artificial intelligence  
5 systems;
- 6 (C) Record of the monitoring, performance  
7 evaluations, and oversight activities; and
- 8 (D) Documentation of findings and actions taken to  
9 address any deficiencies identified through the  
10 monitoring or performance evaluations.

11 **§321- Rules.** The department of health, in coordination  
12 with the department of business, economic development, and  
13 tourism, shall adopt rules pursuant to chapter 91 to implement  
14 this part. The rules shall include but not be limited to the  
15 qualifications, experience, and expertise required for an  
16 artificial intelligence oversight personnel and the frequency of  
17 regular performance evaluations of artificial intelligence  
18 systems required to be performed by certain health care  
19 providers."

20 SECTION 2. This Act shall take effect on January 30, 2050;  
21 provided that section 1 shall take effect on July 1, 2028.



**Report Title:**

DOH; Health Care Providers; Artificial Intelligence; Patient Interaction; Consequential Decisions; Disclosure; Notice; Oversight; Performance Evaluations; Recordkeeping; Rules

**Description:**

Requires health care providers using artificial intelligence (AI) in patient interactions to disclose to the patient that the patient is interacting with artificial intelligence. Requires health care providers using AI in making consequential decisions relating to the patient to provide certain notice and statements to the patient; maintain a qualified AI oversight personnel who shall be a natural person that reviews, evaluates, and validates or overrides AI outputs; monitor and conduct regular performance evaluations of their AI systems; implement procedures to address identified deficiencies; and maintain certain records. Requires the Department of Health to adopt rules. Implementation effective 7/1/2028. Effective 1/30/2050. (SD1)

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